

117TH CONGRESS
1ST SESSION

H. R. 2631

To amend titles XVIII and XIX of the Social Security Act to provide for coverage of peripheral artery disease screening tests furnished to at-risk beneficiaries under the Medicare and Medicaid programs without the imposition of cost-sharing requirements, to amend title XXVII of the Public Health Service Act to require group health plans and health insurance issuers offering group or individual health insurance coverage to provide coverage for such screening tests furnished to at-risk enrollees of group health plans and group or individual health insurance coverage without the imposition of cost sharing requirements, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 16, 2021

Mr. PAYNE (for himself, Mr. GALLEGOS, Mr. RUSH, Mr. TAKANO, Mr. GRIJALVA, Ms. PORTER, Mr. SOTO, Mr. BUTTERFIELD, Mr. VAN DREW, Ms. PRESSLEY, and Mr. SIRES) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend titles XVIII and XIX of the Social Security Act to provide for coverage of peripheral artery disease screening tests furnished to at-risk beneficiaries under the Medicare and Medicaid programs without the imposition of cost-sharing requirements, to amend title XXVII of the Public Health Service Act to require group health plans and health insurance issuers offering group or

individual health insurance coverage to provide coverage for such screening tests furnished to at-risk enrollees of group health plans and group or individual health insurance coverage without the imposition of cost sharing requirements, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; FINDINGS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Amputation Reduction and Compassion Act of 2021” or
6 the “ARC Act of 2021”.

7 (b) FINDINGS.—Congress makes the following find-
8 ings:

9 (1) Atherosclerosis occurs when blood flow is
10 reduced because arteries become narrowed or
11 blocked with fatty deposits.

12 (2) Atherosclerosis is responsible for more
13 deaths in the United States than any other condi-
14 tion, and heart attacks, resulting from clogged coro-
15 nary arteries, are the leading cause of death in
16 America.

17 (3) Atherosclerosis also occurs in the legs and
18 is known as peripheral artery disease (in this sub-
19 section referred to as “PAD”) and having PAD sig-
20 nificantly increases the risk for heart attack, stroke,
21 amputation, and death.

1 (4) While most Americans are aware of atherosclerosis in the heart, many Americans have never
2 heard of PAD and Americans with PAD are often
3 unaware of the serious risks of the disease.

5 (5) An estimated 21 million Americans have
6 PAD, and about 200,000 of them—disproportionately minorities—suffer avoidable amputations every
7 year as a result of such disease.

9 (6) According to the Dartmouth Atlas, amputation risks for African Americans living with diabetes
10 are as much as four times higher than the national
11 average.

13 (7) Data analyses have similarly found that Native Americans are more than twice as likely to be subjected to amputation and Hispanics are up to 75 percent more likely to have an amputation.

17 (8) Fifty-two percent of patients with an above-the-knee amputation and 33 percent of patients with a below-the-knee amputation will die within two years of their amputation.

21 (9) Screening and arterial testing for PAD is cost-effective and should be part of routine medical care.

(10) Once PAD is detected, amputations and deaths can be reduced through the use of national, evidence-based PAD care guidelines.

(11) Americans with a PAD diagnosis are associated with a 67 percent increase in the risk of cardiac death compared to people without a PAD diagnosis. Consequently, screening for PAD enables health care professionals to identify cardiac risk factors earlier and take proactive measures to reduce the risk of cardiac death.

11 SEC. 2. PERIPHERAL ARTERY DISEASE EDUCATION PRO- 12 GRAM.

13 Part P of title III of the Public Health Service Act
14 (42 U.S.C. 280g et seq.) is amended by adding at the end
15 the following new section:

16 "SEC. 399V-7. PERIPHERAL ARTERY DISEASE EDUCATION
17 PROGRAM.

18 "(a) ESTABLISHMENT.—The Secretary, acting
19 through the Director of the Centers for Disease Control
20 and Prevention, in collaboration with the Administrator
21 of the Centers for Medicare & Medicaid Services and the
22 Administrator of the Health Resources and Services Ad-
23 ministration, shall establish and coordinate a peripheral
24 artery disease education program to support, develop, and
25 implement educational initiatives and outreach strategies

1 that inform health care professionals and the public about
2 the existence of peripheral artery disease and methods to
3 reduce amputations related to such disease, particularly
4 with respect to at-risk populations.

5 “(b) AUTHORIZATION OF APPROPRIATIONS.—There
6 is authorized to be appropriated to carry out this section
7 such sums as may be necessary for each of fiscal years
8 2022 through 2026.”.

9 **SEC. 3. MEDICARE COVERAGE OF PERIPHERAL ARTERY**

10 **DISEASE SCREENING TESTS FURNISHED TO**
11 **AT-RISK BENEFICIARIES WITHOUT IMPOSI-**
12 **TION OF COST SHARING REQUIREMENTS.**

13 (a) IN GENERAL.—Section 1861 of the Social Secu-
14 rity Act (42 U.S.C. 1395x) is amended—

15 (1) in subsection (s)(2)—

16 (A) in subparagraph (GG), by striking
17 “and” at the end;

18 (B) in subparagraph (HH), by striking the
19 period at the end and inserting “; and”; and

20 (C) by adding at the end the following new
21 subparagraph:

22 “(II) peripheral artery disease screening
23 tests furnished to at-risk beneficiaries (as such
24 terms are defined in subsection (III)).”; and

1 (2) by adding at the end the following new sub-
2 section:

3 “(III) PERIPHERAL ARTERY DISEASE SCREENING
4 TEST; AT-RISK BENEFICIARY.—(1) The term ‘peripheral
5 artery disease screening test’ means—

6 “(A) noninvasive physiologic studies of extrem-
7 ity arteries (commonly referred to as ankle-brachial
8 index testing);

9 “(B) arterial duplex scans of lower extremity
10 arteries vascular; and

11 “(C) such other items and services as the Sec-
12 retary determines, in consultation with relevant
13 stakeholders, to be appropriate for screening for pe-
14 ripheral artery disease for at-risk beneficiaries.

15 “(2) The term ‘at-risk beneficiary’ means an indi-
16 vidual entitled to, or enrolled for, benefits under part A
17 and enrolled for benefits under part B—

18 “(A) who is 65 years of age or older;

19 “(B) who is at least 50 years of age but not
20 older than 64 years of age with risk factors for ath-
21 erosclerosis (such as diabetes mellitus, a history of
22 smoking, hyperlipidemia, and hypertension) or a
23 family history of peripheral artery disease;

1 “(C) who is younger than 50 years of age with
2 diabetes mellitus and one additional risk factor for
3 atherosclerosis; or

4 “(D) with a known atherosclerotic disease in
5 another vascular bed such as coronary, carotid, sub-
6 clavian, renal, or mesenteric artery stenosis, or ab-
7 dominal aortic aneurysm.

8 “(3) The Secretary shall, in consultation with appro-
9 priate organizations, establish standards regarding the
10 frequency for peripheral artery disease screening tests de-
11 scribed in subsection (s)(2)(II) for purposes of coverage
12 under this title.”.

13 (b) INCLUSION OF PERIPHERAL ARTERY DISEASE
14 SCREENING TESTS IN INITIAL PREVENTIVE PHYSICAL
15 EXAMINATION.—Section 1861(ww)(2) of the Social Secu-
16 rity Act (42 U.S.C. 1395x(ww)(2)) is amended—

17 (1) in subparagraph (N), by moving the mar-
18 gins of such subparagraph 2 ems to the left;
19 (2) by redesignating subparagraph (O) as sub-
20 paragraph (P); and

21 (3) by inserting after subparagraph (N) the fol-
22 lowing new subparagraph:

23 “(O) Peripheral artery disease screening
24 tests furnished to at risk-beneficiaries (as such
25 terms are defined in subsection (III)).”.

1 (c) PAYMENT.—

2 (1) IN GENERAL.—Section 1833(a) of the So-
3 cial Security Act (42 U.S.C. 1395l(a)) is amended—

4 (A) in paragraph (1)—

5 (i) in subparagraph (N), by inserting
6 “and other than peripheral artery disease
7 screening tests furnished to at-risk bene-
8 ficiaries (as such terms are defined in sec-
9 tion 1861(l))” after “other than personal-
10 ized prevention plan services (as defined in
11 section 1861(hhh)(1))”;

12 (ii) by striking “and” before “(DD)”;

13 and

14 (iii) by striking “such service;” at the
15 end and inserting the following: “, and
16 (EE) with respect to peripheral artery dis-
17 ease screening tests furnished to at-risk
18 beneficiaries (as such terms are defined in
19 section 1861(l)), the amount paid shall be
20 100 percent of the lesser of the actual
21 charge for the services or the amount de-
22 termined under the payment basis deter-
23 mined under section 1848”; and

24 (B) in paragraph (2)—

(i) in subparagraph (G), by striking
“and” at the end;

6 (iii) by inserting after subparagraph
7 (H) the following new subparagraph:

8 “(I) with respect to peripheral artery disease
9 screening tests (as defined in paragraph (1) of sec-
10 tion 1861(l)) furnished by an outpatient depart-
11 ment of a hospital to at-risk beneficiaries (as defined
12 in paragraph (2) of such section), the amount deter-
13 mined under paragraph (1)(EE),”.

1 Security Act (42 U.S.C. 1395l(t)(1)(B)(iv)) is
2 amended—

3 (A) by striking “, or personalized” and in-
4 serting “, personalized”; and

5 (B) by inserting “, or peripheral artery
6 disease screening tests furnished to at-risk
7 beneficiaries (as such terms are defined in sec-
8 tion 1861(l)(l))” after “personalized prevention
9 plan services (as defined in section
10 1861(hhh)(1))”.

11 (4) CONFORMING AMENDMENT.—Section
12 1848(j)(3) of the Social Security Act (42 U.S.C.
13 1395w-4(j)(3)) is amended by striking “(2)(FF)
14 (including administration of the health risk assess-
15 ment),” and inserting “(2)(FF) (including adminis-
16 tration of the health risk assessment), (2)(II)”.

17 (d) EXCLUSION FROM COVERAGE AND MEDICARE AS
18 SECONDARY PAYER FOR TESTS PERFORMED MORE FRE-
19 QUENTLY THAN ALLOWED.—Section 1862(a)(1) of the
20 Social Security Act (42 U.S.C. 1395y(a)(1)) is amended—

21 (1) in subparagraph (O), by striking “and” at
22 the end;

23 (2) in subparagraph (P), by striking the semi-
24 colon at the end and inserting “, and”; and

1 (3) by adding at the end the following new sub-
2 paragraph:

3 “(Q) in the case of peripheral artery dis-
4 ease screening tests furnished to at-risk bene-
5 ficiaries (as such terms are defined in section
6 1861(l)(l)), which are performed more frequently
7 than is covered under such section;”.

8 (e) AUTHORITY TO MODIFY OR ELIMINATE COV-
9 ERAGE OF CERTAIN PREVENTIVE SERVICES.—Section
10 1834(n) of the Social Security Act (42 U.S.C. 1395m(n))
11 is amended—

12 (1) by redesignating subparagraphs (A) and
13 (B) of paragraph (1) as clauses (i) and (ii), respec-
14 tively, and moving the margins of such clauses, as
15 so redesignated, 2 ems to the right;

16 (2) by redesignating paragraphs (1) and (2) as
17 subparagraphs (A) and (B), respectively, and mov-
18 ing the margins of such subparagraphs, as so redes-
19 gnated, 2 ems to the right;

20 (3) by striking “CERTAIN PREVENTIVE SERV-
21 ICES” and all that follows through “any other provi-
22 sion of this title” and inserting: “CERTAIN PREVEN-
23 TIVE SERVICES.—

24 “(1) IN GENERAL.—Notwithstanding any other
25 provision of this title”; and

1 (4) by adding at the end the following new
2 paragraph:

3 “(2) INAPPLICABILITY.—The Secretarial au-
4 thority described in paragraph (1) shall not apply
5 with respect to preventive services described in sec-
6 tion 1861(ww)(2)(O).”.

7 (f) EFFECTIVE DATE.—The amendments made by
8 this section shall apply with respect to items and services
9 furnished on or after January 1, 2022.

10 **SEC. 4. MEDICAID COVERAGE OF PERIPHERAL ARTERY**
11 **DISEASE SCREENING TESTS FURNISHED TO**
12 **AT-RISK BENEFICIARIES WITHOUT IMPOSI-**
13 **TION OF COST SHARING REQUIREMENTS.**

14 (a) IN GENERAL.—Section 1905 of the Social Secu-
15 rity Act (42 U.S.C. 1396d) is amended—

16 (1) in subsection (a)—

17 (A) in paragraph (30), by striking “and”
18 at the end;

19 (B) by redesignating paragraph (31) as
20 paragraph (32); and

21 (C) by inserting after paragraph (30) the
22 following new paragraph:

23 “(31) peripheral artery disease screening tests
24 furnished to at-risk beneficiaries (as such terms are
25 defined in subsection (hh)); and”; and

1 (2) by adding at the end the following new sub-
2 section:

3 “(hh) PERIPHERAL ARTERY DISEASE SCREENING
4 TEST; AT-RISK BENEFICIARY.—

5 “(1) PERIPHERAL ARTERY DISEASE SCREENING
6 TEST.—The term ‘peripheral artery disease screen-
7 ing test’ means—

8 “(A) noninvasive physiologic studies of ex-
9 tremity arteries (commonly referred to as ankle-
10 brachial index testing);

11 “(B) arterial duplex scans of lower extrem-
12 ity arteries vascular; and

13 “(C) such other items and services as the
14 Secretary determines, in consultation with rel-
15 evant stakeholders, to be appropriate for
16 screening for peripheral artery disease for at-
17 risk beneficiaries.

18 “(2) AT-RISK BENEFICIARY.—The term ‘at-risk
19 beneficiary’ means an individual enrolled under a
20 State plan (or a waiver of such plan)—

21 “(A) who is 65 years of age or older;

22 “(B) who is at least 50 years of age but
23 not older than 64 years of age with risk factors
24 for atherosclerosis (such as diabetes mellitus, a
25 history of smoking, hyperlipidemia, and hyper-

1 tension) or a family history of peripheral artery
2 disease;

3 “(C) who is younger than 50 years of age
4 with diabetes mellitus and one additional risk
5 factor for atherosclerosis; or

6 “(D) with a known atherosclerotic disease
7 in another vascular bed such as coronary, ca-
8 rotid, subclavian, renal, or mesenteric artery
9 stenosis, or abdominal aortic aneurysm.

10 “(3) FREQUENCY.—The Secretary shall, in con-
11 sultation with appropriate organizations, establish
12 standards regarding the frequency for peripheral ar-
13tery disease screening tests described in subsection
14 (a)(31) for purposes of coverage under a State plan
15 under this title.”.

16 (b) NO COST SHARING.—

17 (1) IN GENERAL.—Subsections (a)(2) and
18 (b)(2) of section 1916 of the Social Security Act (42
19 U.S.C. 1396o) are each amended—

20 (A) in subparagraph (F), by striking “or”
21 at the end;

22 (B) in subparagraph (G), by striking “;
23 and” and inserting “, or”; and

24 (C) by adding at the end the following new
25 subparagraph:

1 “(H) peripheral artery disease screening
2 tests furnished to at-risk beneficiaries (as such
3 terms are defined in section 1905(hh)); and”.

4 (2) APPLICATION TO ALTERNATIVE COST SHAR-
5 ING.—Section 1916A(b)(3)(B) of the Social Security
6 Act (42 U.S.C. 1396o-1(b)(3)(B)) is amended by
7 adding at the end the following new clause:

8 “(xii) Peripheral artery disease
9 screening tests furnished to at-risk bene-
10 ficiaries (as such terms are defined in sec-
11 tion 1905(hh)).”.

12 (c) MANDATORY COVERAGE.—Section
13 1902(a)(10)(A) of the Social Security Act (42 U.S.C.
14 1396a(a)(10)(A)) is amended by striking “and (30)” and
15 inserting “(30), and (31)”.

16 (d) CONFORMING AMENDMENTS.—

17 (1) Section 1902(nn)(3) of the Social Security
18 Act (42 U.S.C. 1396a(nn)(3)) is amended by strik-
19 ing “following paragraph (30)” and inserting “fol-
20 lowing paragraph (32)”.

21 (2) Section 1905(a) of the Social Security Act
22 (42 U.S.C. 1396d(a)) is amended by striking “fol-
23 lowing paragraph (30)” and inserting “following
24 paragraph (32)”.

1 **SEC. 5. REQUIREMENT FOR GROUP HEALTH PLANS AND**
2 **HEALTH INSURANCE ISSUERS OFFERING**
3 **GROUP OR INDIVIDUAL HEALTH INSURANCE**
4 **COVERAGE TO PROVIDE COVERAGE FOR PE-**
5 **RIPHERAL ARTERY DISEASE SCREENING**
6 **TESTS FURNISHED TO AT-RISK ENROLLEES**
7 **WITHOUT IMPOSITION OF COST SHARING RE-**
8 **QUIREMENTS.**

9 (a) IN GENERAL.—Subsection (a) of section 2713 of
10 the Public Health Service Act (42 U.S.C. 300gg–13) is
11 amended to read as follows:

12 “(a) COVERAGE OF PREVENTIVE HEALTH SERV-
13 ICES.—

14 “(1) IN GENERAL.—A group health plan and a
15 health insurance issuer offering group or individual
16 health insurance coverage shall, at a minimum, pro-
17 vide coverage for and shall not impose any cost shar-
18 ing requirements for—

19 “(A) evidence-based items or services that
20 have in effect a rating of ‘A’ or ‘B’ in the cur-
21 rent recommendations of the United States Pre-
22 ventive Services Task Force;

23 “(B) immunizations that have in effect a
24 recommendation from the Advisory Committee
25 on Immunization Practices of the Centers for

1 Disease Control and Prevention with respect to
2 the individual involved;

3 “(C) with respect to infants, children, and
4 adolescents, evidence-informed preventive care
5 and screenings provided for in the comprehen-
6 sive guidelines supported by the Health Re-
7 sources and Services Administration;

8 “(D) with respect to women, such addi-
9 tional preventive care and screenings not de-
10 scribed in subparagraph (A) as provided for in
11 comprehensive guidelines supported by the
12 Health Resources and Services Administration
13 for purposes of this subparagraph; and

14 “(E) with respect to at-risk enrollees, pe-
15 ripheral artery disease screening tests.

16 “(2) PERIPHERAL ARTERY DISEASE SCREENING
17 TEST; AT-RISK ENROLLEE.—For purposes of para-
18 graph (1)(E):

19 “(A) PERIPHERAL ARTERY DISEASE
20 SCREENING TEST.—The term ‘peripheral artery
21 disease screening test’ means—

22 “(i) noninvasive physiologic studies of
23 extremity arteries (commonly referred to
24 as ankle-brachial index testing);

1 “(ii) arterial duplex scans of lower ex-
2 tremity arteries vascular; and

3 “(iii) such other items and services as
4 the Secretary determines, in consultation
5 with relevant stakeholders, to be appro-
6 priate for screening for peripheral artery
7 disease for at-risk enrollees.

8 “(B) AT-RISK ENROLLEE.—The term ‘at-
9 risk enrollee’ means an individual enrolled in a
10 group health plan or group or individual health
11 insurance coverage—

12 “(i) who is 65 years of age or older;

13 “(ii) who is at least 50 years of age
14 but not older than 64 years of age with
15 risk factors for atherosclerosis (such as di-
16 abetes mellitus, a history of smoking,
17 hyperlipidemia, and hypertension) or a
18 family history of peripheral artery disease;

19 “(iii) who is younger than 50 years of
20 age with diabetes mellitus and one addi-
21 tional risk factor for atherosclerosis; or

22 “(iv) with a known atherosclerotic dis-
23 ease in another vascular bed such as coro-
24 nary, carotid, subclavian, renal, or mesen-

1 teric artery stenosis, or abdominal aortic
2 aneurysm.

3 “(C) FREQUENCY.—The Secretary shall,
4 in consultation with appropriate organizations,
5 establish standards regarding the frequency for
6 peripheral artery disease screening tests de-
7 scribed in paragraph (1)(E) for purposes of
8 coverage under this section.

9 “(3) CLARIFICATION REGARDING BREAST CAN-
10 CER SCREENING, MAMMOGRAPHY, AND PREVENTION
11 RECOMMENDATIONS.—For the purposes of this Act,
12 and for the purposes of any other provision of law,
13 the current recommendations of the United States
14 Preventive Service Task Force regarding breast can-
15 cer screening, mammography, and prevention shall
16 be considered the most current other than those
17 issued in or around November 2009.

18 “(4) RULE OF CONSTRUCTION.—Nothing in
19 this subsection shall be construed to prohibit a plan
20 or issuer from providing coverage for services in ad-
21 dition to those recommended by the United States
22 Preventive Services Task Force or to deny coverage
23 for services that are not recommended by such Task
24 Force.”.

1 (b) EFFECTIVE DATE.—The amendment made by
2 subsection (a) shall apply with respect to plan years begin-
3 ning on or after January 1, 2022.

4 SEC. 6. DISALLOWANCE OF PAYMENT FOR NONTRAUMATIC

5 AMPUTATION SERVICES FURNISHED WITH-

6 OUT ANATOMICAL TESTING SERVICES.

7 Section 1834 of the Social Security Act (42 U.S.C.
8 1395m) is amended by adding at the end the following
9 new subsection:

10 "(z) DISALLOWANCE OF PAYMENT FOR NONTRAU-
11 MATIC AMPUTATION SERVICES FURNISHED WITHOUT
12 ANATOMICAL TESTING SERVICES.—

13 “(1) IN GENERAL.—In the case of nontrau-
14 matic amputation services furnished by a supplier on
15 or after January 1, 2022, to an individual entitled
16 to, or enrolled for, benefits under part A and en-
17 rolled for benefits under this part, for which pay-
18 ment is made under this part, payment may only be
19 made under this part if—

20 “(A) such supplier furnishes anatomical
21 testing services to such individual during the 3-
22 month period preceding the date on which such
23 nontraumatic amputation services is furnished;
24 or

1 “(B) such individual has a pre-existing
2 dysfunctional or unsalvageable limb, life-threat-
3 ening sepsis, intractable infection, extensive
4 gangrene or necrotic tissue loss beyond salvage,
5 a poor functional status, severe dementia, or a
6 short life expectancy after shared decision-mak-
7 ing with a health care team and patient, family,
8 or caregiver.

9 “(2) DEFINITIONS.—In this subsection:

10 “(A) ANATOMICAL TESTING SERVICES.—
11 The term ‘anatomical testing services’ means
12 arterial duplex scanning, computed tomography
13 angiography, and magnetic resonance
14 angiography.

15 “(B) NONTRAUMATIC AMPUTATION SERV-
16 ICES.—The term ‘nontraumatic amputation
17 services’ means amputations as a result of ath-
18 erosclerotic vascular disease or a related comor-
19 bidity of such disease (including diabetes).”.

20 **SEC. 7. DEVELOPMENT AND IMPLEMENTATION OF QUALITY**

21 **MEASURES.**

22 (a) DEVELOPMENT.—The Secretary of Health and
23 Human Services (referred to in this section as the “Sec-
24 retary”) shall, in consultation with relevant stakeholders,
25 develop quality measures for nontraumatic, lower-limb,

1 major amputation that utilize appropriate diagnostic
2 screening (including peripheral artery disease screening)
3 in order to encourage alternative treatments (including
4 revascularization) in lieu of such an amputation.

5 (b) IMPLEMENTATION.—After appropriate testing
6 and validation of the measures developed under subsection
7 (a), the Secretary shall incorporate such measures in qual-
8 ity reporting programs for appropriate providers of serv-
9 ices and suppliers under the Medicare program under title
10 XVIII of the Social Security Act (42 U.S.C. 1395 et seq.),
11 including for purposes of—

12 (1) the merit-based incentive payment system
13 under section 1848(q) of such Act (42 U.S.C.
14 1395w–4(q));

15 (2) incentive payments for participation in eligi-
16 ble alternative payment models under section
17 1833(z) of such Act (42 U.S.C. 1395l(z));

18 (3) the shared savings program under section
19 1899 of such Act (42 U.S.C. 1395jj);

20 (4) models under section 1115A of such Act
21 (42 U.S.C. 1315a); and

22 (5) such other payment systems or models as
23 the Secretary may specify.

